

June 20, 2023

The Honorable Xavier Becerra, Secretary
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building, Mail Stop 7033A
330 C Street SW
Washington, DC 20201

Submitted electronically via www.regulations.gov

Re: RIN 0955-AA03; Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule

Dear Secretary Becerra:

Kaiser Permanente appreciates the opportunity to provide comments on the above-captioned Proposed Rule,<sup>1</sup> which would establish new requirements for health information technology (health IT) developers, update certification criteria and implementation specifications, and adopt enhancements to support information sharing.

The Kaiser Permanente Medical Care Program<sup>2</sup> is the largest private integrated health care delivery system in the United States, with more than 12.7 million members in eight states and the District of Columbia. Kaiser Permanente's mission is to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve.

Kaiser Permanente shares the Department of Health and Human Services (HHS) Office of the National Coordinator's (ONC) interest in advancing interoperability, and we appreciate efforts to enhance health IT certification and reduce burden and costs. We offer the following comments for consideration.

## **GENERAL COMMENTS**

Interoperability continues to evolve rapidly with multiple changes to state and federal regulatory frameworks that will become effective over the next several years. We are concerned these changes will create material, unnecessary administrative burden with negative consequences for care quality and the cost of health care if they are not effectively coordinated. For example, we are concerned that this Proposed Rule does not include new requirements for developers of certified health IT and electronic health records (EHR) to build appropriate standards-based functionality to accept and interact with the Prior Authorization Requirements, Documentation and Decision application programming interface (API) that was proposed in the Centers for Medicare & Medicaid Services (CMS) Advancing Interoperability and Improving Prior Authorization

<sup>&</sup>lt;sup>1</sup> 88 Fed. Reg. 23746 (April 18, 2023).

<sup>&</sup>lt;sup>2</sup> Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., one of the nation's largest not-for-profit health plans, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and more than 600 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente's members.

Processes proposed rulemaking.<sup>3</sup> We recommend that ONC and CMS develop a roadmap with associated timelines of all upcoming changes to standards and exchange requirements across agencies to ensure there is coordinated process that recognizes and accounts for interdependencies. Similarly, the Centers for Disease Control and Prevention (CDC) Data Modernization Initiative<sup>4</sup> and Public Health Data Strategy<sup>5</sup> includes plans for important interoperability requirements that are not coordinated with ONC's requirements for reporting systems. We recommend that ONC better coordinate with CDC as well.

Further, while health IT industry organizations and accredited developers continue to rapidly produce new standards, the Department has not yet established a consistent adoption process nor appropriate timeframes for implementation of these new standards. This lack of consistency creates confusion and makes it difficult to keep pace with technological changes. For example, The United States Core Data for Interoperability Standard (USCDI) Version 2 was adopted through a voluntary process known as standards version advancement process (SVAP) while ONC proposes to adopt USCDI Version 3 in this Proposed Rule. We recommend that ONC establish and clearly define criteria to determine when a standard, or version of a standard, will be adopted via regulatory process or voluntary process to eliminate confusion and promote a consistent process. We also recommend that ONC consider moving any further development of USCDI to a national consensus-based standards organization.

We are also concerned that some items listed in the USCDI contain data elements that lack a defined standard. We urge ONC to emphasize that data elements named in standard sets that do not have an American National Standards Institute (ANSI)-accredited or Technical Barriers to Trade (TBT)-compliant<sup>6</sup> defined underlying coding or terminology standard are optional and not required to be implemented.

# ONC CERTIFICATION CRITERIA FOR HEALTH IT AND DISCONTINUING YEAR THEMED "EDITIONS"

ONC proposes discontinuing year-themed editions and establishing a single set of certification criteria, "ONC Certification Criteria for Health IT." Kaiser Permanente supports this change; we clearly see the benefit of this approach to streamline certification processes. However, we are concerned that providers will have difficulty confirming adoption of the most current certified EHR technology (CEHRT) version needed to meet Medicare Promoting Interoperability Program requirements. We recommend that CMS and ONC develop a process for providers to demonstrate compliance for each criterion without referencing a year-themed edition.

#### NEW AND REVISED STANDARDS AND CERTIFICATION CRITERIA

# **USCDI Version 3 and C-CDA Companion Guide Updates**

<sup>&</sup>lt;sup>3</sup> 87 Fed. Reg. 76238 (Dec. 13, 2022)

<sup>&</sup>lt;sup>4</sup> Centers for Disease Control and Prevention. (April 4, 2023). *Data Modernization Initiative*. <a href="https://www.cdc.gov/surveillance/data-modernization/index.html">https://www.cdc.gov/surveillance/data-modernization/index.html</a>.

<sup>&</sup>lt;sup>5</sup> Centers for Disease Control and Prevention. (April 12, 2023). *Public Health Data Strategy*. https://www.cdc.gov/ophdst/public-health-data-strategy/index.html.

<sup>&</sup>lt;sup>6</sup> Office of the United States Trade Representative. (n.d.) *Technical Barriers to Trade*. <a href="https://ustr.gov/trade-agreements/wto-multilateral-affairs/wto-issues/technical-barriers-trade">https://ustr.gov/trade-agreements/wto-multilateral-affairs/wto-issues/technical-barriers-trade</a>.

ONC proposes to adopt USCDI Version 3 as the new baseline for certification.

We are generally supportive of adopting USCDI Version 3 due to the increased functionality it provides. However, this version significantly expands the number and type of data classes and elements and will require a significant amount of time and effort for EHR vendors to develop and providers to update their systems and workflows. We are concerned that the proposed effective date of January 1, 2025 will not provide sufficient time for implementation, particularly in light of other requirements and interdependencies. For example, in this Proposed Rule ONC proposes to move from Release 2 to Release 3 of the Health Level Seven International (HL7) Consolidated Clinical Document Architecture (C-CDA) Companion Guide by January 1, 2025; however, Release 3 does not adequately support USCDI Version 3. In general, we recommend that future certification updates take effect no sooner than 24 months after the effective date of the final rule to allow adequate time for systems development, testing, and implementation. In this case we recommend that ONC wait to adopt USCDI Version 3 until after Release 4 of the C-CDA Companion Guide is finalized, because Release 4 will have appropriate guidance and clarifications for specifying data in USCDI Version 3. We also recommend aligning the implementation dates to no sooner than January 1, 2026 for both USCDI Version 3 and C-CDA Release 4.

We appreciate that moving to USCDI Version 3 will expand data classes and elements to better capture information related to social determinants of health (SDOH) to address the needs of underserved communities and promote health equity. However, we are concerned about the availability, reliability, quality, and validity of some of these data classes and elements, particularly those related to SDOH. SDOH survey instruments and questionnaires lack sufficient guidance, and the process for collection of the data is immature and disjointed, leading to inconsistent capture and variation in the data. We recommend ONC ensure that there is clear guidance regarding the data standards as well as the survey instruments and other approaches to collect the data prior to requiring implementation of USCDI Version 3.

ONC also proposes to make coding requirement changes for certification of Sex Assigned at Birth, Sex for Clinical Use, Sexual Orientation, and Gender Identity. We support these stratifications because it will allow for better capture of sex and gender information to inform care. However, we recommend that these changes be made within the USCDI definitions instead of adopting standards in regulation to provide flexibility and agility as these emerging standards continue to develop.

## **Electronic Case Reporting**

ONC proposes to require that Health IT Modules support electronic case reporting (eCR) using consensus-based, industry-developed HL7 CDA and Fast Healthcare Interoperability Resources (FHIR) standards.

We are generally supportive of the proposed certification criteria for eCR intended to improve public health reporting. However, for this improved functionality to be useful, state and local public health agencies will need to be capable of interacting with EHRs using the new standards. We recommend that ONC publish and maintain a master list of U.S. public health data standards and work with state and local public health agencies to ensure technical readiness for their adoption and implementation. We also recommend that ONC require EHRs to be capable of using both the

HL7 CDA electronic initial case report (eICR) and the HL7 FHIR eICR Implementation Guide (IG) to give providers the option of using either standard based on their technical capabilities.

We also caution that, in some cases, use of the eICR tool can result in data disclosures beyond what is needed to fulfill the purpose of the public health request. For example, the eICR tool has inappropriately sent data from patients with a negative test of a reportable condition or contained extraneous PHI. We urge ONC to evaluate the minimum necessary set of data elements required to be provided across different condition groupings and clarify associated regulatory requirements to ensure that public health agencies are sent only the required data elements when triggered by an appropriate test or finding. Given the above, we strongly recommend that ONC make the eICR submission requirement optional until the data disclosure issue can be resolved and provide additional guidance regarding how to meet minimum necessary requirements under the Health Insurance Portability and Accountability (HIPAA) Privacy Rule ("Privacy Rule") when reporting public health information. If ONC does not wish to make eICR an optional requirement in the interim, we recommend that ONC allow the electronic transmission of initial case reports via an alternative or non-certified modality as agreed upon by the State or Local Health Jurisdiction (LHJ) until the minimum necessary data disclosure issue can be resolved.

# **Decision Support Interventions and Predictive Models**

ONC proposes to revise existing clinical decision support (CDS) criteria to reflect specified contemporary and emerging software functionalities that aid user decision-making in health care, including artificial intelligence (AI) and machine learning (ML).

Kaiser Permanente commends ONC for addressing transparency of decision support interventions (DSIs), and we support the spirit of these requirements. Creating clear and actionable guidelines will beneficially impact the development of DSIs and help ensure that those used within certified health IT are Fair, Appropriate, Valid, Effective and Safe (FAVES). However, we are concerned with the potential burden that these new requirements will place on the developers of certified health IT and on the providers that use the systems. Overly prescriptive requirements could hinder the development of new DSIs and increase costs for purchasers of certified health IT solutions. We recommend that ONC focus on desired functional outcomes and provide IT developers flexibility to achieve these objectives, rather than impose rigid requirements that do not allow for continued innovation and evolution of the technology. We also recommend that ONC adopt a phased implementation approach to allow IT developers sufficient time to develop the in-depth governance and validation processes needed to meet these requirements.

#### Predictive Decision Support Intervention

Kaiser Permanente supports the proposed definition that describes a diverse group of AI-based tools and delineates between predictive and evidence-based DSIs. While we support the proposed definition of "Predictive DSI", we are concerned that these requirements could be extended to health care organizations that develop DSIs for internal uses. We strongly recommend that ONC clarify that these regulatory requirements would not apply to health care providers that have developed their own tools for internal use regardless of whether they are enabled by or interface with the EHR the provider uses.

#### **FAVES**

We generally support the creation and definitions associated with the Fair, Appropriate, Valid, Effective and Safe (FAVES) framework and find that it incorporates the most relevant issues associated with Predictive DSIs. As recommended above, implementation of the principles, supporting infrastructure and verification of the risk model should be left to the developers and the users of the DSI, so that each organization can best determine how to comply with the overarching principles.

## Fair

We understand the impetus to have unbiased decision support; however, medical care decision-making requires special consideration because it is often appropriately biased towards certain types of patient populations in accordance with accepted standards of care. For example, many types of cancer screening begin at specified ages, and certain types of tests and therapies are offered based on sex identified at birth (e.g., cervical cancer or prostate cancer screening). We recommend that ONC clarify that the FAVES principle of "Fair" does not impede clinical care and the appropriate, intentional selection of population cohorts in accordance with accepted standards of care.

#### Safe

All interventions, including predictive DSIs, carry some level of risk, and it can be a challenge to determine whether probable benefits outweigh probable risks. We recommend that ONC provide guidance to assist entities making this determination in accordance with the "Safe" principle.

# Risk Management

ONC proposes to require certified health IT developers to employ or engage in risk management of predictive DSIs.

Kaiser Permanente supports the emphasis on transparency for Predictive DSIs, including both technical and organizational competencies. The proposed risk management practices of risk analysis, risk mitigation and governance are essential for ensuring the trustworthiness of predictive DSIs, and we support the proposal's efforts towards promoting transparency and accountability within health care. We recommend ONC align with and integrate the National Institute of Standards and Technology (NIST) Artificial Intelligence Risk Management Framework as both approaches continue to evolve.

We also support the proposed intervention risk management (IRM) certification requirement and accompanying risk management practices. We request that ONC clarify the level of detail necessary for the IRM summaries and recommend that entities be permitted to exclude or redact confidential or proprietary information. This will ensure that developers of CEHRT and Health IT Modules may not require disclosure of proprietary and confidential information to interface with their technology.

We agree with the need to provide organizational and socio-technical competencies used in the development of Predictive DSIs. While risk management practices are critical to the transparency

of a DSI, we do not find them to be appropriate measures of organization and socio-technical competencies. We recommend that ONC clearly explain in the final rule how the enumerated risk management practices interact with the measurement of organizational and socio-technical competencies in the development and use of predictive DSIs.

#### Source Attributes

ONC proposes to require certified heath IT developers to enable consistent and routine electronic access to technical and performance information on predictive DSIs.

We are concerned that the proposed source attribute disclosure requirements could compromise patient privacy, and we recommend that ONC clarify the granularity of data elements DSI developers will have to disclose. For example, it should be sufficient to disclose that Race was a source data element in creating the DSI, as opposed to disclosing the individual's race.

We also recommend that ONC clarify whether the proposed source attributes will be considered the minimum set of attributes or the complete set of attributes that must be addressed to meet CEHRT status, in accordance with FAVES, described above.

We again request that ONC focus on desired functional outcomes and provide IT developers technical flexibility to achieve these objectives while balancing privacy, security, and innovation.

# Request for Comment

ONC seeks input on how implementation and use of FAVES DSI can be seen as a shared responsibility across developers of certified health IT and their customers; on issues the public believes the Department should consider addressing related to health equity, information privacy, information security, patient safety and data stewardship while enabling trusted development and uses of health data to advance individuals' well-being and overall technology innovation, including AI, ML and algorithms in health care; and on how ONC can further support standardization and harmonization related to Electronic Data Source, Capture and Use.

We recommend that ONC continue to leverage technical data standards developed by voluntary consensus-based standards development organizations such as HL7 and other accredited standards developing organizations (SDOs). We also recommend that ONC investigate how de-identified data from multiple health care organizations may be combined safely and accurately to develop predictive DSI models without violating HIPAA. The Federated Learning concept should be explored as a potential means to increase usable data for models while protecting patient privacy. Additionally, to increase transparency and foster trust, we suggest that ONC develop more education, outreach, and communications about use of individuals' health care data in DSI models.

#### Standardized API Revisions and Related API Conditions

ONC proposes to revise the "Standardized API For Patient and Population Services" certification criteria. We agree with and support these revisions along with reorganization of the structure of proposed API-related standards for certification to delineate the purpose and scope more clearly for each type of standard or implementation specification.

# SMART Application

ONC proposes to adopt the Substitutable Medical Applications, Reusable Technologies (SMART) Application Launch Framework Implementation Guide Release 2.0.0 ("SMART V2"). Kaiser Permanente generally supports adoption of SMART V2, but we are concerned that the proposed adoption timeframe of January 1, 2025 does not give organizations sufficient time to test and implement necessary changes to systems and processes. We recommend that ONC require adoption of SMART V2 no earlier than January 1, 2026.

#### FHIR US Core Implementation Guide STU Version 5.0

ONC proposes to adopt the FHIR US Core IG v5.0.1. We are concerned that Version 5.0.1 of the HL7 FHIR US Core Implementation Guide may be unable to fully support USCDI Version 3, since it was only officially published earlier this year and has had limited testing and use. We recommend ONC make adoption of FHIR US Core IG v5.0.1 optional through January 1, 2026, and consider adopting a future version, likely Version 6, as the required standard after January 1, 2026. We also recommend ONC allow the SVAP process to move the industry to newer versions of the FHIR standards rather than adopting in regulation.

## Publication of Service Base URLs

ONC proposes to require that service base URLs be formatted in FHIR "Endpoint" resource format and published in US Core "Organization" resource format. We support the proposal to adopt a standard FHIR "Endpoint" resource format and include specific identification and demographic information for Service Base URLs. We further recommend that ONC develop and make available nationally a standardized, API-accessible, real-time directory of FHIR Endpoints and Service Base URLs to support health information exchanges.

#### **Patient Demographics and Observations Certification Criterion**

ONC proposes to update certain data elements in USCDI related to Sex (Assigned at Birth), Sexual Orientation, and Gender Identity. Kaiser Permanente supports the proposed adoption of updated standards for patient demographics and observation. We recommend that ONC finalize these changes as specified by the HL7 Gender Harmony Project, which would require health IT developers to capture source documents when recording sex and/or gender information. This will provide health IT developers an opportunity to further differentiate between sex or gender information that exists in a record from Sex for Clinical Use (SFCU) intended to be used for clinical decision-making and information related to gender identity and expression. We agree that the proposed extended timeframe of January 1, 2026 is the earliest possible date for implementation due to the additional complexity associated with this option.

#### **Patient Requested Restrictions Criterion**

ONC proposes to add a new certification criterion and revise existing certification criteria to support additional tools for implementing patient request privacy restrictions. Kaiser Permanente supports consumer privacy rights and protections, and we believe it is important to empower patients with access to and control over their health information. However, we are concerned about potential negative indirect or secondary implications of implementing a process to restrict uses and

disclosures of health data in response to a patient request and encourage ONC to balance any additional consumer rights with these considerations as well as operational and technical challenges.

The proposed certification requirements would establish functional capabilities within EHRs to electronically segment data upon patient request, subject to provider approval. We are concerned that segmenting portions of the medical record or restricting user access would be very disruptive to care delivery workflows and create barriers to care coordination. Significant patient safety and care quality issues could arise if complete medical information is not available to treating providers. For example, serious harm could occur if a provider is not aware of all the medications a patient is currently taking or has recently taken and prescribed a medication or treatment that is contraindicated. We are also concerned that inconsistent approval or application of the functional capability across providers and health organizations could cause patient confusion and mistrust. We strongly urge ONC to limit the scope of this proposal to specifically exclude treatment as defined in the Privacy Rule from patient requests to restrict data or limit user access.

Additionally, implementation of this capability would be extremely complex with significant negative impacts to system access, control design, and system performance. While there have been important recent advances in methods of segmenting health information (e.g., standards for data segmentation, security labels, confidentiality and sensitivity tagging), implementation of these methods in both the use and disclosure of health information remains prohibitively complex and burdensome. This is particularly true with clinical notes, where it is extremely difficult or operationally infeasible to segment specific sections of notes connected with or referring to restricted data elements. In addition to the difficulty, we are concerned that implementing such complex functionality could lead to system performance degradation.

ONC solicits feedback on whether the functionality should allow patients to terminate restrictions and whether Privacy Rule provisions for emergency disclosures should override or terminate the restriction. We believe that patients should have the right to terminate restrictions upon request and recommend that this be included as a necessary element of the functionality. We also recommend permitting emergency disclosures; however, we believe that functionality should be added later due to the complexity it adds and expectations in the volume and types of data that will be subject to restrictions.

#### Alternative Proposals for Patient Requested Restrictions

In addition to the primary proposal above, ONC seeks feedback on a set of alternative proposals for the new certification criterion. We reiterate our earlier concerns related to patient safety and care quality in addition to potential issues with system performance and resource costs. We strongly urge ONC to limit the scope of this proposal to specifically exclude treatment as defined in the Privacy Rule from patient requests to restrict data or limit user access.

We recommend that adoption and use of the HL7 data segmentation for privacy (DS4P) and Healthcare Classification System (HCS) Security Label Vocabulary be optional and initially limited to certain specified use cases (such as only certain data classes in USCDI Version 3). This progressive transition will allow for better testing and demonstration of these technologies before they are widely required.

Finally, we recommend that ONC apply the requirement to both CDA and FHIR standards. If ONC must prioritize between the standards, we suggest that CDA be completed first.

# INSIGHTS CONDITION AND MAINTENANCE OF CERTIFICATION REQUIREMENTS (EHR REPORTING PROGRAM)

ONC proposes to establish a new Insights Condition and Maintenance Certification to provide transparent reporting to address information gaps in the health IT marketplace and provide insights on the use of specific certified health IT functionalities.

While we agree with implementation of an Insights Program as part of the Condition and Maintenance of Certification, we are concerned about the implications for users of certified systems, specifically providers. Most EHR vendors do not have full access to the health information maintained in the EHR systems of clients, and it is not clear how EHR vendors would be able to access the data necessary to generate and report on these measures. We recommend that ONC clarify how EHR vendors would access data to populate required reports while taking steps to reduce provider administrative burden and protect patient confidentiality.

We also recommend that ONC phase-in the number of proposed measures over several years to reduce administrative burden. We are concerned that the number of proposed reporting requirements is too ambitious and would distract vendors from developing other solutions necessary to support patient care and address compliance requirements.

#### INFORMATION BLOCKING

#### **Defined Terms**

"Offer Health Information Technology"

ONC proposes to define what it means to "offer health information technology" for purposes of information blocking. We generally support the proposed clarification and recommend ONC include contractors in the list of enumerated roles in the third exception. Providers often contract with firms and individuals that provide all manner of IT and technology support services, including to their EHR systems, IT infrastructure and circle of support applications. We also recommend that ONC clarify that the definition excludes subsidy arrangements between health care entities, such as a health plan and community provider.

Self-Developer Health Care Providers

ONC proposes to clarify the definition of "health IT developer of certified health IT". We support ONC's clarification.

#### **Exceptions**

*Infeasibility* 

ONC proposes to clarify the scope of the infeasibility exception of the information blocking provision and include additional conditions.

# Third-Party Seeking Modification Use

We generally agree with the proposed changes in this section and support the addition of the new Third-Party Seeking Modification Use condition. However, we do not support including the "limited duration" provision because there are not appropriate safeguards in place nor sufficient guidance to indicate when a third-party should be allowed to modify data in a providers EHR. We also recommend that ONC include use case examples in the preamble to illustrate the type of situations where this exception would apply.

#### Manner Exception Exhausted

We strongly support addition of the new Manner Exception Exhausted provision because it promotes interoperability based on standards as opposed to unique or non-scalable solutions. Allowing actors to focus resources on standards and certified health IT solutions incentivizes both actors and requestors to adopt certified health IT. We recommend actors be required to offer a minimum of two alternative manners, with at least one manner using certified technology or content and transport standards. This is particularly important for large organizations that handle large volumes with a variety of requests. We recommend requiring two alternative manners for USCDI, but requiring only one alternative certified or standard based method for non-USCDI EHI data

We do not recommend that ONC clarify the term "substantial number" to mean a fixed number for the same reasons outlined in the preamble. We also do not support including more textual specificity or clarity regarding the term "similarly situated to the requestor" because the same verbiage is used under the Fees and Licensing Exceptions.

Lastly, we recommend that ONC clarify that this condition only includes the current method of sharing data. Actors should not be held to continue data sharing that occurred under previous exchange methods that have since been updated or replaced.

#### Manner Exception – TEFCA Reasonable and Necessary Activities

ONC proposes to add a new TEFCA condition to the proposed revised Manner Exception. Kaiser Permanente is generally supportive of this exception; however, we note that the exception is unlikely to be used in practice because the responder must be able to provide electronic health information (EHI) through the Trusted Exchange Framework and Common Agreement (TEFCA) to invoke it. TEFCA currently only requires exchange using USCDI Version 1 and most responders will be unable to send all EHI through this method; alternate manners of exchange will be required to comply with a request for complete EHI. Additionally, both the requestor and responder need to be TEFCA participants to invoke this exception, so if both partners have not yet onboarded TEFCA, then the exception cannot be invoked.

We recommend that ONC amend this condition to allow a responder to invoke the exception even if the requestor is not also a TEFCA participant to encourage widespread TEFCA adoption. We also support continued development of additional TEFCA Reasonable and Necessary Activities exceptions to encourage TEFCA adoption.

#### REQUESTS FOR INFORMATION

# **Laboratory Data Interoperability**

ONC seeks feedback that may be used to inform future rulemaking regarding the adoption of standards and certification criteria to advance laboratory data interoperability and exchange. We reiterate our previous statement that ONC should adopt standards that are ANSI-accredited or TBT-compliant. Kaiser Permanente recommends that ONC consider adopting HL7 Genomics Reporting Implementation Guide ("Genomics IG") to support the movement of genomics into standard clinical care. Work is actively taking place to improve the maturity of the Genomics IG, specifically within GenomeX, which is housed within the CodeX FHIR Accelerator as a foundational domain. No significant changes are expected; therefore, ONC can review the current version of the Genomics IG as the version which will be published as the fully mature standard.

#### **FHIR Standards**

FHIR Subscriptions

ONC seeks input on the maturity of resources in the FHIR Release 4 standard and whether the FHIR Subscriptions capability aligns with the adoption of the FHIR Release 5 standard. Our view is that this standard is not mature enough and has not been sufficiently tested to be adopted. We recommend defining a minimum set of Subscription topics that can be consistently adopted by health IT developers to avoid unnecessary complexity.

# Clinical Decision Support Hooks

ONC seeks input on the scope and maturity of the FHIR CDS Hooks v1.0, which is being considered for future inclusion in the Program. We recommend adoption of this functionality, as it is sufficiently mature and has undergone several years of development and testing.

FHIR Standard for Scheduling

ONC seeks input on the maturity and scope of the SMART Scheduling Links Implementation Guide, which is being considered for future inclusion in the Program. As this functionality is sufficiently mature, we recommend adoption.

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Kaiser Permanente appreciates ONC's consideration of our comments, and we look forward to continued collaboration. Please feel free to contact me at <a href="mailto:Jamie.Ferguson@kp.org">Jamie.Ferguson@kp.org</a> or Megan Lane at <a href="mailto:Megan.A.Lane@kp.org">Megan.A.Lane@kp.org</a> with questions or if we can provide additional information.

Sincerely,

Jamie Ferguson

Vice President, Health IT Strategy and Policy

Kaiser Foundation Health Plan, Inc.

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